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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,710	04/22/2005	Takeshi Ito	KUZ-0022	5270

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03/06/2009

EXAMINER
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FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1619

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/527,710		ITO ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	SHANON A. FOLEY		1619	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejections below are maintained for reasons of record:

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (US 6,139,866) in view of Tsuruda et al. (CA 2 424 579).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Urquhart et al. (US 4,031,894).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Scholz et al. (US 5,750,136).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Higo et al. (US 5,866,157).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Zaffaroni (US 3,598,122) and further in view of Kochinke (US 5,350,581).

### ***Response to Arguments***

On page 2 of applicant's arguments, applicant states the following:

At the outset, Applicants respectfully disagree with the Examiner that teaching of Tsuruda et al. that a base containing less than 1% PIB will lack adhesive strength is indicative of results exemplified in the Table at page 20 of the instant application not being unexpected.

Although the complete meaning of this statement is not understood, every attempt will be made to address applicant's traversal. In the paragraph bridge pages 21-22, Tsuruda et al. specifically state in lines 5-6:

“A base containing [polyisobutylene] in an amount of less than 1% by mass will lack the adhesive strength.”

The results in the Table on page 20 of the instant disclosure echo the precautions of Tsuruda et al. since examples 1-4 use 8% PIB, 10% PIB, 13% PIB and 10% PIB, respectively. The examples presented in the Table on page 20 do not use less than 1% PIB and therefore, do not demonstrate an unexpected result.

Applicant further argues that the percentage (1%) are outside the claimed range shown to be critical to the properties of the instant invention.

Applicant's arguments have been fully considered, but are found unpersuasive. The recitations of instant claim 1 do not require any particular percentage. The only numerical requirement in claim 1 is ratios ranging between 2:3 or 3:2 of PIB:SIS, respectively. Therefore, the percentages of styrene/isoprene/styrene (SIS) or polyisobutylene (PIB) in claim 1 can be any value, as long as the ratios are met. As explained in the Office action mailed December 4, 2007, Chono et al. discloses the weight ratio of polyisobutylene to styrene/isoprene/styrene is in the range of 1:1 and 1:4 (col. 3, lines 9-10), which encompasses the instant ratios. However, instant claim 8 requires that the PIB be between 8-15 wt %. Chono et al. fails to disclose these weight percent ranges. However, Tsuruda et al. discloses an adhesive patch having combination of

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styrene/isoprene/styrene block copolymer and polyisobutylene (pg. 23, lines 20-24). Tsuruda et al. discloses the total amount of polyisobutylene be in the range of 1-20% by weight (pg. 21, lines 9-13). This range taught by Tsuruda et al. would include ranges between 8-15 wt %.

Tsuruda et al. also teach that the amount of styrene/isoprene/styrene block copolymer being in the range of 15-30% by weight (pg. 20, lines 16-21). From the teachings of Tsuruda et al., one of ordinary skill in the art at the time the invention was made could have chosen any particular combination of PIB and SIS within the ranges taught to arrive at a specific ration, including a 2:3 ration or a 3:2 ration, or any range between the two. It would have been an obvious design choice to one of ordinary skill in the art to modify the amount of the polymers, as desired, in order to adjust the adhesive strength and adhesion properties, as taught by Tsuruda et al. (pg. 23, line 10 - pg. 24, line 20). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discover the optimum or working ranges involves only routine skill in the art (emphasis added). *In re Aller*, 105 USPQ 233. In the instant case, Chono et al. teaches that the instant ratios between PIB:SIS are 1:1, which teaches the ratios used in the instant examples 1-4 on page 20 of the instant disclosure. Regarding the obviousness of attaining ratios ranging from 2:3 and 3:2, as instantly recited, both Chono et al. and Tsuruda et al. teach varying ratios between PIB and SIS. Additionally, Tsuruda et al. teaches weight percentages of each ingredient that would have rendered the ratio range instantly claimed prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Applicant further argues that the instant patch is for maintaining a long-term drug efficacy. Applicant states that the ion pair type adhesive patch, taught by Chono et al. is unsuitable for extending the drug efficacy of fentanyl beyond one day.

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Applicant's arguments have been fully considered, but are found unpersuasive for a few reasons. "Long-term efficacy" is not defined in the instant disclosure and since it is a relative term, one day could be considered "long-term". Further, the phrase is an intended use. The claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the combination of teachings of Tsuruda et al. and Chono et al. meet all of the required limitations for claims 1-3 and 7-9. If Chono et al. met all of the limitations, as a single teaching, then the reference would have been applied under the statute for anticipation.

Applicant summarizes all of the teachings of the remaining references and concludes that the remaining references fail to cure the deficiencies of Chono et al. and Tsuruda et al.

In response, since there are no deficiencies discovered between the teachings of Chono et al. and Tsuruda et al., the rejections are maintained for reasons of record.

### ***Conclusion***

This is an RCE of applicant's earlier Application No. 10/527,710. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on M-F 5:30 AM-3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/  
Primary Examiner  
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